

# New Facility Handbook

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#### Introduction

The Kansas Meat and Poultry Inspection Act governs the meat inspection program of the Kansas Department of Agriculture. The regulations which state inspected plants must follow included in this handbook are reproduced from the Kansas Meat Inspection Regulations Handbook and the code of Federal Regulations, Title 9, Parts 200 to the end. The purpose of this handbook is to provide guidance for the regulatory requirements of sanitation and the design and construction of meat and poultry slaughter and processing plants. To offer further explanation of each regulatory requirement, included are commentaries reflecting the experience of inspection and industry personnel.

The Kansas Meat Inspection Act, as amended by the legislature in 2003, applies to livestock (cattle, buffaloes, sheep, swine, goats, domesticated deer, all creatures of the ratite family that are not indigenous to this state, including but not limited to ostriches, emus and rheas or horses, mules or other equines), domestic rabbits and poultry, or the meat or meat products of poultry or poultry products thereof, which are capable of use as human food and which may be brought into any slaughtering, canning, salting, packing or similar establishment where inspection under this act is maintained. Livestock shall not include buffalo or domesticated deer slaughtered for sport or recreational purposes.

As described in K.S.A. 65-6a34, registration and annual fees must be made with the secretary for persons engaging in business, in or for intrastate commerce, as a meat broker, animal food manufacturer, wholesaler, public warehouseman or operate a packing house, sausage plant, poultry packing plant, slaughterhouse or poultry dressing plant. According to K.S.A. 65-6a27, of the Kansas Meat and Poultry Inspection Act,

# (a) It shall be a violation of this act for any person:

- (1) To slaughter any livestock, domestic rabbits or poultry, except in compliance with this act;
- (2) To prepare any meat, meat food product, poultry or poultry product which is capable of use as human food, at any establishment preparing such products, except in compliance with the requirements of this act;
- (3) To do, with respect to any meat, meat food product, poultry or poultry product which is capable of use as human food, any act, while being distributed or transported or while being held for sale after such distribution or transportation, which has the effect of causing such products to be adulterated or misbranded; or
- (4) To engage in a business specified in subsection (a) of K.S.A. 65-6a34 and amendments thereto or engage in business or operate a packing house, sausage plant, poultry packing plant, slaughterhouse or poultry dressing plant unless such person is currently registered with the secretary in accordance with the provisions of K.S.A. 65-6a34 and amendments thereto and has paid the fees required for the current calendar year as required by that section.

# (b) It shall be a violation of this act for any person to sell, offer or expose for sale or to distribute or transport:

(1) Any carcass or part thereof which is capable of use as human food, or any meat, meat food product, poultry or poultry product which is adulterated or misbranded; or (2) Any carcass or part thereof which is capable of use as human food, or any meat, meat food product, poultry or poultry product, which is required to be inspected

under the provisions of this act, unless such products have been so inspected and passed.

# Sanitation Performance Standards and Sanitation Standard Operating Procedures

The Kansas Department of Agriculture is adopting FSIS' new food safety strategy, by moving away from a command and control methodology toward a more flexible regulatory approach based on Hazard Analysis and Critical Control Point (HACCP) philosophy and performance standards. Performance standards set the results to be achieved but not the specific means used to achieve those results. Though establishments can use different and varying means to meet the performance standards—the required results must always be the same: establishments must prevent insanitary conditions that could lead to adulterated product. Performance standards are results-oriented. Performance standards provide flexibility allowing innovation and the discovery of new ways and technologies for achieving desired results. Further, performance standards more clearly differentiate between inspection's responsibility and the establishment's. Performance standards neither lessen inspection's authority nor weaken the statutory and regulatory requirements that official meat and poultry establishments must meet to maintain sanitary conditions.

The Kansas Meat & Poultry Inspection Act establishes that a meat or poultry product is adulterated if it has "been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." When Inspection personnel inspect the grounds, facilities, and equipment at meat and poultry establishments, they are looking for these insanitary conditions. To determine whether conditions in or around an establishment are insanitary, inspection program personnel must ask the question posed by the Act: "Could these conditions cause product to be contaminated with filth or cause product to be unsafe?"

There are so many ways that insanitary conditions can cause product to be adulterated that they cannot all be listed. Instead, this guidance explains the intent of the sanitation regulations and gives examples of some of the ways inspection program personnel can determine whether a meat or poultry establishment is operating under insanitary conditions.

Inspected establishments must meet two sets of regulations concerning sanitation: The Sanitation Standard Operating Procedures (Sanitation SOP) requirements and the Sanitation Performance Standards (SPS). Under the Sanitation SOP requirements, each establishment must develop, implement, and maintain written procedures for the actions it takes daily, before and during operations, to prevent product from being directly contaminated and adulterated. An establishment's Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. The SPS regulations cover all of the other

aspects of plant sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems. Keep in mind that these two sets of regulations overlap somewhat in the plant activities they cover. Also, some establishments may address certain sanitation problems within their HACCP plans.

#### **Sanitation Performance Standards**

#### § 416.1 General rules

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

Proper sanitation is a fundamental requirement under both the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) and the Kansas Meat & Poultry inspection Act. Meat and poultry products produced, packed, or held under insanitary conditions, where they may have become contaminated with filth or may have been rendered injurious to health, are adulterated.

#### § 416.2 Establishment grounds and facilities

(a) Grounds and pest control. The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS personnel. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product.

#### Grounds

Proper maintenance of the grounds about an establishment is essential for ensuring good sanitation. Inspectors will request written designation of the official premises boundaries (FSIS Directive 7640.1, *Inspection Duties Related to Facilities and Equipment, and Plant Operated Quality Control Programs;*http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7640-1Amend1.pdf). Inspectors may use this information as reference when inspecting establishment grounds. Establishments should keep in mind, however, that they are responsible for preventing the adulteration of product even if the cause of the adulteration originates from conditions outside the designated boundaries of the establishment.

#### Pest Control

Proper maintenance of the grounds about an establishment is essential for ensuring good sanitation. The pest management program does not have to be written. FSIS no

longer requires the prior approval of pesticides because prior approval is contrary to the HACCP philosophy where establishments are responsible for identifying hazards and establishing critical controls. These performance standards establish that it is the establishment's responsibility for the safe and effective use and storage of pesticides. The regulations require that documentation substantiating the safety of other chemicals, including pesticides, be made available for inspection to review (416.4 (c)). In most cases the document record will be the "Material Safety Data Sheet."

The FSIS regulations in 9 CFR 416.2 to 416.5 set forth more specific performance standards that each official establishment must meet to prevent the creation of insanitary conditions that could cause the adulteration of meat and poultry products. These regulations provide the sanitation standards the establishment must meet for the Federal or State mark of inspection to be applied to its products. Some of the SPS regulations address conditions within or around the establishment (e.g., ventilation, lighting, facility and equipment construction, and maintenance of the grounds). Other SPS address establishment operations and so may be met by an establishment through its Sanitation SOP (e.g., sanitizing of food contact surfaces) or its HACCP plan (e.g., water reuse).

# § 416.2(b) Construction

- (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.
- (2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product.
- (3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
- (4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

The establishment buildings must be sound and kept in good repair to prevent insanitary conditions or the adulteration of product. Establishments currently maintaining sanitary conditions will not be required to make changes to their construction or layout because of this performance standard.

Some examples of noncompliance with these standards commonly reported by inspectors are listed below. They are not all inclusive; they represent noncompliance only with the performance standards in 416.2(b), provisions (1) through (3).

• Doors not closing tightly allowing the entrance of vermin, dirt, or dust;

- Holes in ceilings or windows allowing the entrance of vermin, dirt, or dust;
- Scaling rust or scaling paint in edible areas on ceilings or walls;
- Walls in production area have mold growth.

Establishments can process, handle, or store edible and inedible product in the same room as long as they are separated by time or space, in a manner sufficient to prevent the adulteration of the edible product or the creation of insanitary conditions.

#### § 416.2(c) Light

Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

FSIS has abolished the specific lighting requirements in the poultry regulations and have combined the separate meat and poultry lighting requirements into one performance standard. While FSIS is giving establishments flexibility in determining lighting requirements, lighting must be adequate in quality and well distributed to allow for the monitoring of sanitary conditions and processing conditions, and to examine product for evidence of adulteration. FSIS is not rescinding the lighting requirements for inspector and reprocessing stations (sections 307.2 and 381.36).

Establishments should keep in mind that their lighting should be sufficient not only to allow their own employees to maintain sanitation and prevent product adulteration, but also to allow inspection personnel to verify that conditions are sanitary and product is not adulterated. This does not mean, however, that lighting sufficiency is to be determined subjectively, by the inspector. Establishments must determine which intensities and qualities of light are appropriate in different processing environments. KDA will direct its inspection personnel to make judgments accordingly.

#### § 416.2(d) Ventilation

Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

Inspection does not expect that an establishment's ventilation will be able to completely eliminate all odors, vapors, and condensation but it must control them as far as necessary to prevent adulteration of product or the creation of insanitary conditions.

In regard to condensation, keep in mind that some forms are unavoidable and acceptable within a food processing environment, since they will neither adulterate product nor create insanitary conditions. Other forms of condensation are expected, but must be controlled by the establishment, and others are unacceptable at any time. Examples of different types of condensation and corresponding inspection responses:

# SITUATIONS INVOLVING CONDENSATION IN WHICH NO ACTION IS REQUIRED

In certain situations, condensation within an official establishment has no affect on product safety, sanitary conditions, or inspection. If inspection program personnel determine that such a situation exists, no action is necessary by him/her or the establishment. Some examples:

- Condensation forms on the underside of a stainless steel vessel lid during cooking.
- The packaging of packaged entrees or soups comes into contact with condensation which has formed as a result of freezing operations.
- Condensation forms on the wall or ceiling of a loading dock where canned products are stored in wrapped boxes on palettes. (Although this situation may not threaten product safety or impede inspection, establishments should avoid allowing excessive condensation to form anywhere food is processed or stored.)

# SITUATIONS IN WHICH CONDENSATION IS EXPECTED AND CONTROLLED BY THE OFFICIAL ESTABLISHMENT

In other situations, establishments expect condensation to form as a result of certain operations and take action to ensure that the condensation does not adulterate product or create insanitary conditions. Such actions must be documented in the establishment's Sanitation Standard Operating Procedures (Sanitation SOP's). Most often, establishments will control such condensation by cleaning and sanitizing, on a daily or as-needed basis, the surface(s) where the condensation is expected to form. Examples of such surfaces include:

- The inside or outside of stainless production chutes.
- Ceilings over open kettle cooking areas and over poultry chill vats.
- The outside of stainless steel ice vats or ice chutes in chill areas.

# SITUATIONS IN WHICH INSPECTION PROGRAM PERSONNEL MUST TAKE ACTION

In some situations, condensation clearly adulterates product, creates insanitary conditions, and/or interferes with inspection. Some examples:

- Heavily beaded condensation forms on a ceiling or wall of a processing area that
  is not regularly cleaned and sanitized in accordance with the establishment's
  SSOP's (an insanitary condition is created that could lead to the adulteration of
  product).
- Condensate from a cooler ceiling drips onto carcasses.
- Condensate from refrigeration unit surfaces, which have not been cleaned and sanitized, drips onto exposed product.

• Condensate from a loading dock ceiling or wall drips onto boxes of boneless beef, breaking down the packaging.

## § 416.2(e) Plumbing

Plumbing systems must be installed and maintained to:

- (1) Carry sufficient quantities of water to required locations throughout the establishment:
  - (2) Properly convey sewage and liquid disposable waste from the establishment;
- (3) Prevent adulteration of product, water supplies, equipment, or utensils, and maintain sanitary conditions throughout the establishment;
- (4) Provide adequate floor drainage in all areas where floors are subject to floodingtype cleaning or where normal operations release or discharge water or other liquid waste on the floor;
- (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge wastewater or sewage and piping systems that carry water for product manufacturing; and
  - (6) Prevent the backup of sewer gases.

#### § 416.2(f) Sewage disposal

Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When these wage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish inspection with the letter of approval from that authority upon request.

It is the responsibility of the establishment to ensure that plumbing and sewage systems provide an adequate supply of potable water and remove waste and sewage from the establishment without adulterating product or creating insanitary conditions.

#### § 416.2(g) Water supply and water, ice, and solution reuse

(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR Part141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply, that has been renewed at least semi-annually.

- 2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.
- (3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse water which has come into contact with raw product may not be used on ready-to-eat product.
- (4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.
- (5) Any water that has never contained human waste and that is free of pathogenic organisms may be used inedible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, flush the bottom of open evisceration troughs, or to wash ante-mortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.
- (6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

The water performance standard makes transparent the current requirement that potable water complies with EPA's National Primary Drinking Water regulations. Certifications of water potability provided by the state or local governments or other responsible entities will show whether water meets the EPA requirements. Some meat and poultry establishments use private wells for their water supply. EPA does not require testing for these water sources. Usually the state or local governments do not test the wells for potability. Most establishments can obtain the needed documentation from private laboratories. The regulations require that documentation certifying the potability of water from private systems be renewed at least semi-annually.

#### § 416.2(h) Dressing rooms, lavatories, and toilets

(1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

- (2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.
- (3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

OSHA has always had standards for lavatories in their regulations (29 CFR 1910.141). These standards should be followed when establishments are constructed. FSIS will no longer dictate the number of lavatories required. Lavatory facilities need to be maintained by the establishment in good repair and in a sanitary manner.

## § 416.3 Equipment and utensils

- (a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained insanitary condition so as not to adulterate product.
- (b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS personnel from inspecting the equipment or utensils to determine whether they are in sanitary condition.
- (c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

Establishments have the flexibility to choose whatever method they want to clean utensils and equipment to ensure that they are maintained in sanitary condition so as not to adulterate product. FSIS has eliminated the requirement that utensils and equipment used to dress diseased meat carcasses be cleaned with either 180 degree F. water or an approved disinfectant. FSIS no longer requires a specific method for the cleaning of utensils and equipment used to dress diseased meat carcasses, although they must still be maintained in a sanitary condition.

#### § 416.4 Sanitary operations

- (a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions or the adulteration of product.
- (b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions or the adulteration of product.
- (c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must used, handled, and stored in a manner that will not adulterate product or

create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection personnel for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

Usually, an establishment cleans its operations once a day; however, some establishments have for some time conducted chemical cleanup procedures less than once a day. Currently, establishments may use extended cleanup procedures without prior approval of FSIS. FSIS expects an establishment to incorporate extended cleanup procedures into its Sanitation SOP's (See 416.12). To ensure that extended cleanup procedures prevent insanitation and the adulteration of product, most establishments will probably conduct microbiological and chemical sampling that evaluates the effectiveness of the extended cleanup. The establishment's Sanitation SOPs records would include the microbiological and chemical data that distinguish acceptable sanitary conditions from marginal or unacceptable sanitary conditions. (See 416.14). During the normal course of an establishment's operations meat and poultry products should not come in contact with non-food contact surfaces. Still if non-food contact surfaces are not properly cleaned and sanitized, insanitary conditions could result, leading to the potential adulteration of product.

FSIS has discontinued approving all nonfood compounds and proprietary substances for use in official meat and poultry establishments. Inspection continues to require that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary substances and nonfood compounds. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available for Inspection's review. The documentation will vary with the nature and intended use of that chemical. For example, for a pesticide, an establishment should have documentation showing that the compound is registered with EPA and the label information for the pesticide. For a chemical sanitizer used on food contact surfaces, an establishment should have documentation showing that the compound complies with the relevant Food and Drug Administration regulations in 21 CFR 178.1010. (Sanitizers meeting this requirement are usually identified as "Food Grade.") Meat and poultry establishments are responsible for ensuring that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately. Establishments are free to choose whatever scientifically supportable method they find effective in limiting microbial growth in their operations.

#### § 416.5 Employee Hygiene

- (a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product.
- (b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must

be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent contamination or adulteration of product.

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination must be excluded from any operations which could result in product adulteration until the condition is corrected.

Specific types of unhygienic practices have been removed from the regulations. Inspection continues to have the authority to take action against any unhygienic practice that could result in insanitary conditions or adulterated product.

#### § 416.6 Tagging insanitary equipment, utensils, rooms or compartments

When a Program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a "U.S. Rejected" tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only a Program employee may remove a "U.S. Rejected" tag.

#### **Sanitation SOPs**

The establishment has the responsibility to develop, implement, and maintain written Sanitation SOPs. The basic regulatory requirements are described in 9 CFR 416.12. At the time inspection is granted, the establishment must have a Sanitation SOP that meets these requirements. Inspection verifies that the written procedures meet the basic regulatory requirements.

#### § 416.11 General rules

Each official establishment shall develop, implement, and maintain writ-ten standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

#### § 416.12 Development of Sanitation SOP's

- (a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
- (b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
- (c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

#### § 416.13 Implementation of SOP's

- (a) Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified.
- (b) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOPs.

Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations.

#### § 416.14 Maintenance of Sanitation SOP's

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

Note: Construction and removal of walls, ceilings, and floors may cause harborage sites for *Listeria monocytogenes* to be dislodged from otherwise protected areas.

#### § 416.15 Corrective Actions

- (a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).
- (b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

#### Examples of noncompliance:

• The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to ensure appropriate disposition of product.

- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to restore sanitary conditions.
- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to prevent recurrence of direct contamination or adulteration of product. This may lead to a trend of repeated noncompliances.

## § 416.16 Recordkeeping requirements

- (a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.
- (b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.
- (c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

#### § 416.17 Agency verification

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

- (a) Reviewing the Sanitation SOP's;
- (b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken:
- (c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and
- (d) Direct observation or testing to assess the sanitary conditions in the establishment.

# **Regulations governing other facility requirements**

## § 305.2 Separation of official establishments.

- (a) Each official establishment shall be separate and distinct from any unofficial establishment except a poultry products processing establishment operated under federal inspection under the Poultry Products Act or under State inspection.
- (c) Inspection shall not be inaugurated in any building, any port of which is used as living quarters, unless the part for which inspection is requested is separated from such quarters by floors, walls, and ceilings of solid concrete, brick, wood, or similar material; and the floors, walls, and ceilings are without openings that directly or indirectly communicate with any part of the building used as living quarters.

#### § 305.3 Sanitation and adequate facilities.

Inspection shall not be inaugurated if an establishment is not in a sanitary condition nor unless the establishment agrees to maintain a sanitary condition and provides adequate facilities for conducting such inspection.

## § 307.1 Facilities for program employees.

Office space, including necessary furnishings, light, heat and janitor service, shall be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and assigned program employees. The space set aside for this purpose shall meet with approval of the supervisor and shall be conveniently located, properly ventilated and provided with lockers suitable for protection and storage of program supplies and with facilities suitable for program employees to change clothing if such facilities are deemed necessary. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing shall be provided by each establishment.

#### § 307.2 Other facilities and conditions to be provided by establishment.

When required by the supervisor, the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions shall be provided by each official establishment.

(a) Satisfactory pens, equipment and assistants for conducting ante-mortem inspection and for separating, marking and holding apart from passed livestock those marked "K.S. suspect" and those marked "K.S. condemned." (Pens, alleys, and runways

shall be paved, drained and supplied with adequate hose connections for cleanup purposes);

- (b) Sufficient light to be adequate for proper conduct of inspection;
- (c) Racks, receptacles, or other suitable devices for retaining such parts as the head, tongue, tail, thymus gland, viscera, and all parts and blood to be used in the preparation of meat food products or medical products, until after the post-mortem examinations is completed, in order that they may be identified in case of condemnation of the carcass; equipment, trucks, and receptacles for the handling of viscera of slaughtered animals so as to prevent contact with the floor and trucks, racks, marked receptacles, tables, and other necessary equipment for the separate and sanitary handling of carcasses or parts passed for cooking;
- (d) Tables, benches, and other equipment on which inspection is to be performed must be of such design, material and construction as to enable program employees to conduct their inspection in a ready, efficient and clean manner;
- (e) Watertight metal trucks or receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned such trucks or receptacles to be marked in a conspicuous manner with the phrase "U.S. Condemned" in letters not less than 2 inches high and, when required by the supervisor, to be equipped with facilities for locking or sealing;
- (f) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for disinfecting all implements used in dressing diseases carcasses, floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;
- (g) In establishments in which slaughtering is done, rooms, compartments, or specially prepared open places, to be known as "final inspection places," at which the final inspection of retained carcasses may be conducted (competent assistants for handling retained carcasses and parts shall be provided by the establishment; final inspection places shall be adequate in size and their rail arrangement and other equipment shall be sufficient to prevent carcasses and parts passed for food or cooking, from being contaminated by contact with condemned carcasses or parts; they will be equipped with hot water, lavatory, sterilizer, tables, and other equipment required for ready, efficient and sanitary conduct of the inspection the floors shall be of such construction as to facilitate the maintenance of sanitary conditions and shall have proper drainage connections and when the final inspection place is part of a larger floor, it shall be separated from the rest of the floor by a curb, railing or otherwise);
- (h)Retention rooms, cages, or other compartments and receptacles in which carcasses and product may be held for further inspection. (These shall be in such number and in such locations as the needs of the inspector in the establishment may require they shall be equipped for secure locking or sealing and shall be held under locks or official seals furnished by the Department, the keys of such locks shall not leave the custody of program employees. Every such room, compartment, or receptacle shall be marked

conspicuously with the phrase "U.S. retained" in letters not less than 2 inches high; rooms or compartments for these purposes shall be secure and susceptible to being kept clean, including a sanitary disposal of the floor liquids; establishment employees shall not enter any retention rooms or compartments or open any retention receptacles unless authorized by program employees);

- (i) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter (tanks or other rendering equipment which, under the regulations in this subchapter, must be sealed, shall be properly equipped for sealing as specified by the regulations in Part 314 of this subchapter or by the supervisor in specific cases);
- (j) Docks and receiving rooms, to be designated by the operator of the official establishment, with the supervisor, for the receipt and inspection of all products as provided in §318.3 of this subchapter;
- (k) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) and official certificates shall be kept when not in use (all such lockers shall be equipped for sealing or locking with locks or seals to be supplied by the Department; the keys of such locks shall not leave the custody of Program employees);
- (1) Sanitary facilities and accommodations as prescribed by §308.4 of this subchapter.
- (m) In addition to any facilities required to accomplish sanitary dressing procedures, the following inspection station facilities for cattle and swine slaughter lines described in §310.1(b) of this subchapter are required:
- (1) An inspection station consisting of 5 feet of unobstructed line space for each head or carcass inspector and, for viscera table kills, 8 feet for each viscera inspector on the inspector's side of the table.
- (2) A minimum of 50 foot-candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass.
- (3) A hand wash lavatory (other than one which is hand operated) furnished with soap, towels, and hot and cold water, and located adjacent to the inspector's work area. In addition, for each head and viscera inspector on cattle slaughter lines, and each head inspector on swine slaughter lines, a sterilizer located adjacent to the inspector's work area.
- (4) For mechanized operations, a line control switch located adjacent to each inspection station.
- (5) Facilities to position tally sheets or other recording devices, such as digital counter, and facilities to contain condemned brands.

(6) For swine slaughter lines requiring three or more inspectors, and for those one- and two-inspector configurations where the establishment installs a mirror: At the carcass inspection station one glass or plastic, distortion-free mirror, at least 5 feet by 5 feet, mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet away, and so mounted that any inspector standing at the carcass inspection station can readily view the back of the carcass.

## § 313.1 Livestock pens, driveways and ramps

- (a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking, and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.
- (b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable construction and maintenance.
- (c) U.S. Suspects (as defined in  $\S 301.2(xxx)$ ) and dying, diseased, and disabled livestock (as defined in  $\S 301.2(y)$ ) shall be provided with a covered pen sufficient, in the opinion of the inspector to protect them from the adverse climatic conditions of the locale while awaiting disposition by the inspector.
- (d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.